

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No
PCT/US2004/040726

International filing date (day/month/year)
06.12.2004

Priority date (day/month/year)
04.12.2003

International Patent Classification (IPC) or both national classification and IPC
C08B37/00

Applicant
UNIVERSITY OF UTAH RESEARCH FOUNDATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2004/040726

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/040726

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-223
Inventive step (IS)	Yes: Claims	
	No: Claims	1-223
Industrial applicability (IA)	Yes: Claims	1-198
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item VIII

Certain observations on the international application

Although claims 1, 14, 24, 25, 45, 46, 47, 48, 60, 61, 62, 63, 68, 69, 70, 71, 72, 73, 74, 82, 83, 84, 85, 99, 117, 118, 128, 147, 150, 151, 154, 155, 159, 166, 173, 185, 195, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 212, 213, 214, 215, 216, 217, 218, 219, 221 and 223 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter.

The aforementioned claims therefore lack conciseness to a severe degree and as such do not meet the requirements of Article 6 PCT.

Reference is made to the following documents:

- D1:** WO 2004/037164 A (UNIVERSITY OF UTAH RESEARCH FOUNDATION; PRESTWICH, GLENN, D; SHU, XIAO) 6 May 2004
- D2:** US-A-5 874 417 (PRESTWICH ET AL) 23 February 1999
- D3:** US-B1-6 630 457 (AESCHLIMANN DANIEL ET AL) 7 October 2003
- D4:** US-A-5 880 270 (BERNINGER ET AL) 9 March 1999

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Novelty

The subject-matter of **claims 1-223** is not novel over the documents D2 and D3 (Article 33(2) PCT).

D2 and D3 are directed to the modification of hyaluronic acid by way of functionalisation with an hydrazide, the crosslinking thereof and the formation of hydrogels, for use as tissue adhesive, tissue separator, drug delivery system, matrix for cell culture and temporary scaffold for tissue regeneration.

2. Inventive step

Since the subject-matter of **claims 1-223** is not novel, the question of inventive step appears to be superfluous (Article 33(3) PCT).

3. Industrial applicability

3.1. The subject-matter of present **claims 1-198** appears to comply with the requirements of industrial applicability as stipulated in Article 33(4) PCT.

3.2. For the assessment of the present **claims 199-223** on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VI

Certain documents cited

Certain published documents (Rule 70.10)

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
D1	06.05.2004	15.05.2003	21.06.2002

This disclosure contains matter related to the subject-matter of **claims 1-223** although it does not constitute prior art within the meaning of rule 64.1(b) PCT. It could, however, be relevant for the assessment of novelty and inventive step, if the priority of the present application has not been validly claimed.